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Cai-Zhong Jiang

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

11/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/669,824 | <b>Applicant(s)</b><br>JIANG ET AL. |  |
|                              | <b>Examiner</b><br>David H. Kruse    | <b>Art Unit</b><br>1638             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/22/09 and 11/19/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,24-33,36-38 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 and 44 is/are allowed.
- 6) ☒ Claim(s) 22,24-33,36-38,41,42 and 45-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment(s)</u> .            |

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed 22 July 2009.
2. Applicants' amendment has put the Specification in compliance with the Sequence Rules, the objection of record is withdrawn.
- 3.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Inventorship***

5. In view of the papers filed 19 November 2009, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Jindong Sun, Kimberly Faye Zobrist-Duff, Jingrui Wu, Changlin Fu, Stanton B. Dotson and Linda L. Lutfiyya.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1638

7. Claims 22, 24-33, 36-38, 41 and 42 remain rejected and claims 45-48 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 April 2009. Applicant's arguments filed 22 July 2009 have been fully considered but they are not persuasive.

Applicants argue that the instant specification has provided a significant number of phylogenetically related AT hook transcription factors, and that each of these polypeptide sequences has a conserved AT hook motif and a second conserved domain that are highly homologous to amino acids 62-70 and 106-201 of G3456 (SEQ ID NO; 14). Applicants argue that the specification has taught "the fragment or domain is a subsequence of the polypeptide that performs at least one biological function of the intact polypeptide in substantially the same manner, or to a similar extent, as does the intact polypeptide. Applicants argue that a polypeptide fragment can comprise a recognizable structural motif or functional domain such as a DNA-binding site or domain that binds a DNA promoter region and fragments can vary in size from as few as 3 amino acid residues to the full length of the intact polypeptide" (page 20, lines 12-19). Applicants argue that the specification has also taught "more closely related transcription factors can share at least about 89% or about 100% identity in their AT-hook domains, and at least about 63%, or at least about 65%...identity with the second

Art Unit: 1638

conserved domain of G1073, (page 36). Applicants argue that the second conserved domains that are highly homologous to that of SEQ ID NO: 14, are present in all the functional sequences as disclosed in Table 1. Applicants argue that Applicants have disclosed that a large number of sequences conferred increased drought tolerance or greater biomass when ectopically expressed in transgenic plants and all of these sequences have the common structural elements, i.e. conserved AT motifs and second conserved domains (also known as the DUF296 domain) (paragraph spanning pages 10-11 of the Remarks). These arguments are not found to be persuasive. The conserved domain (claim 22) represents only 34% of instant SEQ ID NO: 14. Applicants do not provide evidence that this "conserved domain" in association with an AT hook domain describes a transcription factor that "when over-expressed in a transgenic plant confers to the transgenic plant greater drought tolerance or greater biomass relative to a control plant".

Applicants argue that they have provided functionally- and structurally-related polypeptide species that are representative of the claimed genus by having been derived from more evolutionarily diverse species (monocots and eudicots) than the mammals in the example provided by the USPTO. Applicants argue that the variations within plant species from which the sequences are derived reflect the variations of the sequence species within the claimed genus, since the closer two plant species are in phylogeny, the more likely they will have structurally and functionally similar sequences. Applicants argue that they have disclosed a representative number of sequences from diverse plant species, sufficient relevant identifying structure elements, i.e. the AT hook

Art Unit: 1638

motif and the second conserved domain that are highly homologous to those present in G3456, SEQ ID NO: 14, and also functional characteristics, i.e. conferring drought tolerance or greater biomass, coupled with a disclosed correlation between the structure and function (page 14 of the Remarks). These arguments are not found to be persuasive for the reasons given above. The specification at pages 94-95 describes no structural and functional relatedness among these AT-hook transcription factors.

Applicants argue that they have disclosed a soy sequence G3456 (SEQ ID NO: 14), two *Arabidopsis* sequences G1069 (SEQ ID NO: 42) and G2153 (SEQ ID NO: 6) and a rice sequence G3401 (SEQ ID NO: 38); these sequence share 100%, 60.4%, 66.1% and 61.5% sequence identity with SEQ ID NO: 14, respectively (please see Exhibit B). Applicants further disagree that Applicants' evidence of polypeptide sequence identity appear to be directed to species at the extremes of the claimed genus, and do not describe the variation within the genus (page 15, 2<sup>nd</sup> paragraph of the Remarks). But, Applicants' own arguments demonstrate that only the extremes of the claimed genus have been described, not a representative number of species that describe the variation within the genus.

8. Claims 22 and 24-31 remain rejected and claims 45-48 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a recombinant construct comprising a polynucleotide encoding SEQ ID NO: 14 and methods of using same, does not reasonably provide enablement for a recombinant construct comprising a polynucleotide encoding a polypeptide at least 60% or 90% identical to SEQ ID NO: 14 and methods of using same. The specification does not

Art Unit: 1638

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 April 2009. Applicant's arguments filed 22 July 2009 have been fully considered but they are not persuasive.

Applicants argue that they have provided the conserved structure elements of the claimed genus of sequences. Applicants argue that the fully tested polynucleotides conferred drought tolerance and/or greater biomass when overexpressed in a transgenic plant. Applicants argue that these sequences represent a practical sampling of a large number of sequence species. Applicants argue that through these numerous exemplar plant sequence species, Applicants have demonstrated the correlation between the common structure elements and the conserved function. Applicants argue that they have found that a wide variety of plant species have orthologous or closely-related homologous sequences that function as does G3456; the numerous claimed G3456 homologs derived from both eudicots and monocots that have been introduced into plants have been shown to confer greater tolerance to drought or greater biomass relative to control plants when the sequences were overexpressed. Applicants argue that these studies suggested that numerous genes from diverse plant species are likely to function similarly (i.e., by regulating similar target sequences and controlling the same traits) and thus finding and using sequences that function similarly would not require undue effort (p[age 17, 2<sup>nd</sup> paragraph of the Remarks).

Applicants argue that they believe their concrete guidance in the form of working examples address a number of the Examiner's concerns, and weigh in favor of the specification enabling one skilled in the art to make and use the claimed plants.

Applicants argue that assuming that sufficient reason for such doubt could exist, which Applicants dispute, such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling (*In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA ! 971 ); original *emphasis*). Applicants argue that they believe suitable proofs in the form of a one-to-one correlation with structure and function and the breadth of the working examples indicates that the teaching contained in the specification is truly enabling (page 18, 1<sup>st</sup> paragraph of the Remarks).

These arguments are not found to be persuasive. Applicants provide limited guidance on how to make and use the claimed genus of recombinant constructs as broadly claimed. It is recognized in the instant art that AT-hook (a type of HMG protein) proteins appear to play a role in transcription regulation by acting as accessory factors which influence the association of transcription factors with chromatin and act as transcription factor cofactors (Aravind *et al* 1998, Nucleic Acids Research 26(19): 4413-4421, page 4413, right column, 1<sup>st</sup> paragraph). The art teaches that AT-hook motifs seem to be auxiliary elements necessary for cooperation with other DNA-binding activities in the same or different proteins (Aravind *et al* 1998, page 4413, right column 2<sup>nd</sup> paragraph). Aravind *et al* 1998 teaches that the AT-hook is a short stretch of sequence similarity which makes it difficult to detect in conventional searches and discern scores which are statistically significant (page 4414, left column, 2<sup>nd</sup> paragraph).



Art Unit: 1638

Aravind *et al* 1998 in Table 1 on pages 4415-4417 teach that AT-hook proteins have a wide variety of specific functions including enzymatic activity, positive and negative regulation functions, and chromatin structural functions. Hence, given the nature of the invention, the breadth of the claims and the amount of direction or guidance present, it would have required undue trial and error experimentation to make and use the invention as broadly claimed.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 22, 24, 26-29, 31-33, 37-38, 42 and 45-48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin, X (NCBI Accession No. AAF04888, Online, NIH, National Library of Medicine, Bethesda, MD USA; publicly disclosed on 2 November 1999), in view of Sawa *et al* (1999, Genes & Development 13: 1079-1088).

Lin teaches an AT hook transcription factor polypeptide, and polynucleotides encoding same, that comprises a conserved domain that is 80.2% identical to amino acids 106-201 of instant SEQ ID NO: 14. Lin teaches Applicants' SEQ ID NO: 6.

Lin does not teach transgenic plants or methods of making explicitly.

Sawa *et al* teach making transgenic plant using a recombinant construct encoding an AT-hook transcription factor using a CaMV 35S promoter at page 1083.

It would have been *prima face* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Lin to make a transgenic plant transformed with a recombinant construct encoding the AT hook transcription factor using the teachings of Sawa *et al.* Given the teachings of Swaw *et al.*, one of ordinary skill in the art would have had a reasonable expectation of success. Instant claims 45-48 have been included in this rejection based on Applicants' assertion that G2153 (instant SEQ ID NO: 6) is 66.5% identical to SEQ ID NO: 14 at page 15, last two lines of the Remarks filed 22 July 2009. This rejection is made because the Office's search shows Applicants' SEQ ID NO: 6 to be 56.2% identical to Applicants' SEQ ID NO: 14 as shown in the Office action attachment. Instant claims 32 and 33 are deemed obvious because the recited method steps would have been considered obvious; growing a transgenic plant cell in to a transgenic plant is obvious in view of the teachings of Swaw *et al.*

### **Conclusion**

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1638

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Claims 43 and 44 are allowed.

13. 22, 24-33, 36-38, 41, 42 and 45-48 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/  
Primary Examiner, Art Unit 1638  
23 November 2009